The Rejection under 35 U.S.C. 112, first paragraph

Claims 11-23 have been rejected under 35 U.S.C. 112, first paragraph, as the Specification is alleged not to reasonably provide enablement for any progenitor cell.

The Patent Office has conceded that the Specification is enabled for cultured cells and bone marrow stromal cells, but it has been alleged that there is no reasonably provided enablement for any progenitor cell.

In the interest of advancing prosecution and without acquiescing to this rejection, claimså 11 and 17 (the independent claims) have been amended to recite that the progenitor cells are cultured cells. It is believed that the amendments made herein render this rejection moot, and the withdrawal of this rejection is respectfully requested.

The Rejections under 35 U.S.C. 103(a)

Claims 11-23 have been rejected under 35 U.S.C. 103(a) as allegedly obvious over United States Patent No. 5,763,416 ('416) or WO 96/39431 in view of United States Patent No. 4,654,084 ('084) and United States Patent No. 5,700,774 ('774). Applicants respectfully traverse this rejection.

The Patent Office has alleged that the '416 patent or WO 96/39431 teaches a method for producing cultured or bone marrow stromal cells for implantation at the site of a bone infirmity transforming with recombinant bone morphogenetic protein. The '416 patent is alleged to suggest the use of PTH in the method, where BMP and PTH can be coexpressed in the target cells and these documents identify the requirement of BMP and/or PTH receptors in the target cells. WO 96/39431 taught BMP-10; '416 taught the use of BMP-2 or other BMPs.

Claims 11-16 specify that the human cell into which the BMP-encoding DNA is introduced is a cultured human progenitor cell or a bone marrow stromal cell and that the BMP to be expressed is BMP-2. By contrast, WO 96/39431 teaches transformation of BMP-10 coding

sequences. The amendment of the present application to specify BMP-2 distinguishes over WO 96/39431.

The Patent Office has maintained that the use of BMP-2 is obvious. Applicants respectfully note that the use of BMP-2 has advantages which the Patent Office has not noted to be associated with BMP-10 or other bone morphogenetic proteins. For example, the Specification at page 47, lines 9-13 indicates that apoptosis appeared to be less in cells transfected with an adenovirus vector encoding BMP-2 than in control cells. The Patent Office has not indicated this observation with BMP-10 or other BMPs. The present application also teaches a positive effect on differentiation and on proliferation (see page 48, lines 21-23) of BMP-2, again expressed via an adenovirus vector. Again, the Patent Office has not pointed to these effects of BMP-2 as compared with other BMPs.

Accordingly, Applicants respectfully submit that the present invention possesses unexpectedly improved results over prior art BMP expression systems, and therefore the present invention is not obvious over the cited art. The withdrawal of the rejection is respectfully requested.

Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by a Petition for Extension of Time (three months) and a check in the amount of $1170 as required under 37 C.F.R. 1.17. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17.

If the amount submitted is incorrect, however, please charge any deficiency or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,

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